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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,845	02/09/2006	Rudolf-Giesbert Alken	82445	5014

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EXAMINER	
NAGUBANDI, LALITHA	
ART UNIT	**PAPER NUMBER**
1621	
MAIL DATE	**DELIVERY MODE**
09/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,845	ALKEN, RUDOLF-GIESBERT	
	Examiner	Art Unit	
	Lalitha Nagubandi	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *amdt6/18/2007.*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,34-55 and 57-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,34-55 and 57-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Office Action

Status of Claims

1-11, and 34-55 and 57-63 are pending. 1-11, and 34-55 and 57-63 are considered for examination in this office action.

Response to Argument

Applicants' remarks, filed on June 18th, 2007, with respect to the previous office action dated February 15th, 2007 have been fully considered.

In view of the amendment to the claim 1, the art rejection 102 (b) with regard to claims 1,2,9, and 10 are herewith withdrawn.

Upon further review of the amended claims the following rejections were made:

New Grounds of Rejections necessitated by amendment

Claim Rejections - 35 USC § 103

Claims 1- 11, 42- 48 and 57-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Putter et al (US Pat No. 3,699,158 dt. Oct. 17th 1972).

The instant claims are directed to various deuterated catecholamine derivatives of the general **formula I,** *currently amended.* Further, pharmaceutical compositions containing deuterated catecholamine derivatives are embodied in the instant application.

Determination of Scope and content of the Prior Art (MPEP § 2141.01)

Putter et al teach selective deuterated compounds/intermediates specifically selective deuterated tyrosine (see column 2, lines 30 – 50,).

Ascertainment of the difference between the Prior Art and Claims (MPEP §2141.02)

The difference between the instant compounds and Putter et al is that the instant compounds require a di deuterated hydroxy attached to the aromatic ring and whereas in the prior art the tyrosine has mono deuterated hyroxy.

Finding of prima facie obviousness – rational and motivation (MPEP § 142-2143)

Accordingly, one of ordinary skill in the art would be motivated to prepare the instant compounds by modifying the process of deuteration depending on the substrate as taught by Putter and a skilled artisan would modify the prior art process by introducing the DOPA or analogues of DOPA and subject them to selective deuteration and an ordinary artisan is expected to have reasonable success in synthesizing the instant product/compositions.

The examiner contends that the above reference is proper and an ordinary artisan would have had a reasonable expectation of success at the time of the instant invention to arrive at the instant compounds/compositions and hence it is prima facie

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,34 – 41 and 49 – 55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1, 34 –41 and 49 –55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the synthesis of the deuterated catecholamine derivatives, does not reasonably provide enablement for a method of treatment of dopamine deficiency diseases or the enlisted diseases in the instant claims.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Enablement is considered in view of the *Wands factors* (MPEP 2164.01 (a)) as the instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the existence of working examples; and (8) the quantity of experimentation necessary. All of the *Wands factors* have been considered with regard to the instant application, with the most relevant factors discussed below.

Nature of the Invention

All of the rejected claims are drawn to an invention which pertains to a method for the treatment of dopamine eficiency diseases or diseases which are based on disrupted tyrosine transport and as enlisted in the instant claims and further the method comprising

administering to a patient in need thereof an effective amount of the dueterated catecholamine derivative according to claim 1 as well as physiologically compatible salt.

Breadth of the Claims

The complex nature of the claims is greatly exacerbated by breadth of the claims. Claims 1,34-41 and 49-55 encompass a method of treatment of acute psychoses and a method for the production of pharmaceuticals for the prophylaxis of psychoses is rather unclear.

Guidance of the Specification/ Working Examples

There is no guidance given by the specification as to what type of administration is rendered to the patient in need.

All of the guidance provided by the specification is directed towards sythesis of deuterated catecholamines in the instant application. (See examples 1 – 7 pages 19 – 24 of the specification).

Predictability of the Art

The instant application is directed to a method of dopamine deficiency diseases, for the treatment of amyotrophic lateral sclerosis. Further, in the treatment of inhibiting prolactin secretion, and a method for the production of pharmaceuticals for the

prophylaxis of psychoses as well as for the treatment of acute psychoses is rather broad and unclear.

In the instant case, the instant methods are highly unpredictable since one skilled in the art cannot fully describe, visualize or recognize the identity of the invention and unable to predict which compound is used in the treatment of which disease.

The amount of Experimentation Necessary

In order to practice claimed invention of one of skilled in the art would have to first envision a combination of appropriate compound or composition and an appropriate model system and test the combination in the model system to determine whether or not the combination is effective or not. If successful, which is unlikely given the lack of significant guidance from the specification, one skilled in the art would have to then either envision a modification of the combination or envision an entirely new combination of the above, and test the desired compound again, whose success is unpredictable. Therefore, it would require undue experimentation to practice the claimed invention to develop deuterated catecholamines as claimed in the instant application.

Hence, the method of treatment as embodied in the instant claims in the absence of the above factors has not been considered as enabled by the instant specification.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

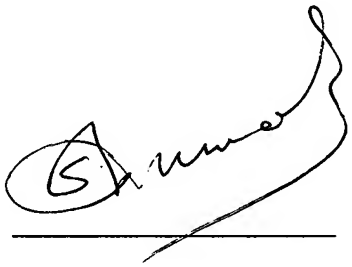
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lalitha Nagubandi whose telephone number is 571 272 7996. The examiner can normally be reached on 6.30am to 3.00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne, Eyler can be reached 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lalitha Nagubandi
Patent Examiner
Technology Center 1600

September 18th, 2007.



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